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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATION

#2

Applicants	:	Douglas G. Evans and John E. Nash
Serial No.	:	09/369,107
Filed	:	August 5, 1999
For	:	TRANSMYOCARDIAL REVASCULARIZATION SYSTEM AND METHOD OF USE
Art Group Unit	:	
Examiner	:	

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR 1.97

Assistant Commissioner for Patents
Washington, D. C. 20231

Sir:

This Information Disclosure Statement is being filed pursuant to 37 CFR 1.97.

The following references are disclosed:

U.S. PATENTS

U.S. Patent No. 3,887,699

U.S. Patent No. 4,658,817

U.S. Patent No. 4,669,473

U.S. Patent No. 5,287,861

U.S. Patent No. 5,500,000

U.S. Patent No. 5,591,159

U.S. Patent No. 5,607,421

U.S. Patent No. 5,655,548

U.S. Patent No. 5,728,114

U.S. Patent No. 5,810,836

FOREIGN PATENTS

International Publication No. WO 97/32551

German Gebrauschmuster No. DE 296 19 029 U1

European Patent Application EP 0 876 803 A2; and

German Patent Application DE 196 45 183 A1

ARTICLES

Angiogenic Therapy of Acute Myocardial Infarction by Intrapericardial Injection of Basic Fibroblast Growth Factor and Heparin Sulfate: An Experimental Study, by Uchida et al., in the American Heart Journal, 130:1182-1188, December 1995;

Basic Fibroblast Growth Factor Enhances The Coupling Of Intimal Hyperplasia And Proliferation Of Vasa Vasorum In Injured Rat Arteries by Edelman, et al. in J. Chin. Invest, Volume 89, February 1992, 465-473;

Basic Fibroblast Growth Factor Improves Myocardial Function In Chronically Ischemic Porcine Hearts, Harada, et al., J. Clin. Invest., Volume 94, August 1994, 623-630;

Biologic Bypass with the Use of Adenovirus-Mediated Gene Transfer of the Complementary Deoxyribonucleic Acid for Vascular Endothelial Growth Factor 121 Improves Myocardial Perfusion and Function in the Ischemic Porcine Heart by Mack et al. in the Journal of Thoracic and Cardiovascular Surgery, 115:168-177, January 1998;

Direct Intraarterial Wall Injection Of Microparticles Via A Catheter: A Potential Drug Delivery Strategy Following Angioplasty by Wilensky, et al., in the American Heart Journal, 1136-1140, October 1991;

Experimental Method For Producing A Collageral Circulation To The Heart Directly From The Left Ventricle by Goldman et al. in the Journal of Thoracic and Cardiovascular Surgery, 31:364-374, March, 1965;

Experimental Use Of A Modified Fibrin Glue To Induce Site-Directed Angiogenesis From The Aorta To The Heart by Fasol et al. in The Journal of Thoracic and Cardiovascular Surgery, Volume 107, 1432-1439, June 1994;

Histological Findings After Transmyocardial Laser Revascularization by Krabatsch, et al., in the Journal of Cardiac Surgery, 11:326-331, 1996;

Local Drug Delivery for the Treatment of Thrombus and Restenosis by Raoul Bonan, M.D. in the Journal of Invasive Cardiology, 8:399-408, October 1996;

Myocardial Revascularization By A New Method Of Carrying Blood Directly From The Left Ventricular Cavity Into The Coronary Circulation by Massimo et al. appearing in J. Thorac. Surg., 34:257-264, August, 1957;

Myocardial Revascularization by Transmyocardial Acupuncture, A Physiologic Impossibility by Pifarre, et al. in the Journal of Thoracic and Cardiovascular Surgery, 58:424-431, September 1969;

New Concepts in Revascularization of the Myocardium by Mirhoseini, et al., in the Ann. Thor. Surg., 45:415-420, April 1988;

Perivascular and Intravenous Administration Of Basic Fibroblast Growth Factor: Vascular And Solid Organ Deposition by Edelman et al., in Proc. Natl. Acad. Sci., USA, Vol. 90, 513-1517, February 1993;

Transmyocardial Acupuncture: A New Approach To Myocardial Revascularization by Sen et al. in the Journal of Thoracic and Cardiovascular Surgery, 50:181-187, August, 1965;

Transmyocardial Laser Revascularization. Histological Features In Human Nonresponder Myocardium by Wintzer, et al., appearing in Circulation, 95(c): 371-375, January 21, 1997;

Transmyocardial Laser Revascularization-Morphologic Pathophysiologic And Historical Principles Of Indirect Revascularization Of The Heart Muscle by Moosdorf, et al., in Z Kardiol, 86(3): 147-164, March, 1997.

Attached is PTO Form 1449 listing the above documents. Also attached herewith is a copy of the documents listed.

The relevance of much of the prior art documents which are cited in the attached form 1449 is set forth on pages 5, 6 7 and 8 of the Specification of the subject application. Those documents identified in the attached form 1449 which are not identified in the subject application's specification will be set forth hereinafter.

United States Letters Patent No. 3,887,699 (Yolles) discloses an article for dispensing drugs. The article is formed of a biodegradable polymeric material and a drug. The drug is intimately dispersed throughout the polymer. The combination of the polymer and drug can be formed into various shapes for implantation.

United States Letters Patent No. 4,669,473 (Richards, et al.) was cited during the prosecution of the parent application for the subject application. The Richards et al. patent basically discloses a surgical fastener arranged to be implanted in body tissue, e.g., bone. The fastener is of a generally T-shaped configuration having a filament connected to the head portion.

United States Letters Patent No. 5,287,861 (Wilk) discloses a collapsible stent for implantation within the wall of a being's heart so that it extends between the left ventricle and the coronary artery.

United States Letters Patent No. 5,500,000 (Feagin et al.) discloses a soft tissue repair system in the form of a suture anchoring member. This reference was also cited during the prosecution of the parent application for the subject application.

United States Letters Patent No. 5,728,114 (Evans, et al.) discloses an apparatus and methods of use to reduce bleeding from the situs of a percutaneous arterial puncture. This reference was also cited during the prosecution of the parent application for the subject application.

United States Letters Patent No. 5,810,836 (Hussein, et al.) discloses a stent for insertion into a heart wall to effect transmyocardial revascularization. This patent also discloses the generation of needle-made or drill channels into the heart wall where the stent is implanted to maintain the patency of the channel.

International Publication WO 97/32551 discloses a TMR stent which is formed of a non-resorbable material, e.g., stainless steel (either uncoated or coated with gold or carbon), carbon, gold and platinum.

German Gebrauchsmuster No. DE 296 19 029 U1 and German Patent Application DE 196 45 183 A1 both disclose a system for transmyocardial revascularization in which a single resorbable suture is introduced into plural channels formed by the mechanical piercing action of a needle. The needle also serves to carry the sutures into the channels.

European Patent Application EP 0 876 803 A2 discloses plural, hollow, TMR stents which are formed of a non-resorbable material, e.g., a plastic material such as high density polyethylene. The stents are provided to produce channels in the myocardium into which blood may flow and prevent closure of those channels, a problem which has characterized prior art transmyocardial revascularization techniques using mechanical means to form the plural lumens or channels in the myocardium.

The publication "Angiogenic therapy of acute myocardial infarction by intrapericardial injection of basic fibroblast growth factor and heparin sulfate: An experimental study" describes use of a catheter system for percutaneous transluminal administration of drugs, e.g., growth factors, through the right atrium into the pericardial cavity.

The publication "Biologic Bypass with the use of Adenovirus-Mediated Gene Transfer of the Complementary Deoxyribonucleic Acid for Vascular Endothelial Growth Factor 121 Improves Myocardial Perfusion and Function in the Ischemic Porcine Heart" describes experiments to improve myocardial profusion.

The publication "Experimental Methods for Producing a Collateral Circulation to the Heart Directly from the Left Ventricle" discloses several experimental methods for myocardial revascularization. One method involves the implantation of

excised perforated carotid arteries into the left ventricular wall. This publication also examines the use of implanted perforated polyethylene tubing in a similar fashion.

The publication "Local Drug Delivery for the Treatment of Thrombus and Restenosis" discusses that the cardiac community has recently begun to augment standard catheter-based treatment techniques with devices that provide local delivery of medications to the treated site. This local administration of drugs has shown promise for counteracting clotting, reducing inflammatory responses, and blocking proliferative responses.

The publication "Myocardial revascularization by transmyocardial acupuncture, A physiologic impossibility" evaluates the feasibility of direct myocardial revascularization from the left ventricle through artificially created channels.

The publication "Transmyocardial laser revascularization. Histological features in human nonresponder myocardium" discusses a histological study of the creation of transmyocardial channels from the epicardium to the left ventricular cavity with the use of a laser.

The publication "Direct Intraarterial Wall Injection of Microparticles via a Catheter: a Potential Drug Delivery Strategy Following Angioplasty" by Wilensky R.L. et al., American Heart Journal October 1991 discusses the delivery of 5um particles potentially therapeutic agents, e.g., proteins, into the arterial wall using a porous balloon catheter in a rabbit model of atherosclerosis. Polystyrene microspheres were delivered into the diseased femoral arteries of rabbits at 3 and 5atm injection pressure. The presence of the microspheres in the arteries were analyzed over 14 days. The microspheres were found in the intima, media, and adventitia of the arteries at up to 14 days after implantation. The

theory is proposed that the microspheres entered the arterial wall through cracks in the plaque formed during angioplasty of the lesion.

The publication "Basic Fibroblast Growth Factor Enhances the Coupling of Intimal Hyperplasia and Proliferation of Vaso Vasorum in Injured Rat Arteries" by Edelman E. R. et al., J. Clin. Invest. 92;89:465-473, Feb. 1992 discloses a study of the mitogenic and angiogenic properties of bFGF. Rat carotid arteries were injured by balloon denudation and then bFGF was placed in the perivascular space surrounding the injured carotids. The bFGF was released over 2 weeks from heparin-Sepharose beads encapsulated within calcuim alginate microcapsules. The result was profound angiogenesis within and surrounding the polymer caspule containing bFGF and significant SMC proliferation within the vessel related to the increased vaso vasorum.

The publication "Perivascular and Intravenous Administration of Basic Fibroblast Growth Factor: Vascular and Solid Organ Deposition," by Edelman E. R. et al., Proc. Natl. Acad. Sci. USA 1993;90:1513-1517, Feb. 1993 discloses a study of a comparison of the efficiency and kinematics of intravenous and perivascular bFGF delivery. The bFGF was delivered as an IV bolus or implanted in the perivascular tissue surrounding the carotid artery in rats. The max serum levels of bFGF following the IV bolus was within 1 minute of injection and the serum half life was about 3 minutes. To achieve controlled release, bFGF was incorporated into heparin-Sephrose beads encapsulated within calcuim alginate microcapsules. The microcapsules delivered 40 times more bFGF to the artery wall than the IV injection. When delivered with an IV injection, bFGF was 5 to 30 fold more abundant in solid organs than when delivered perivascularly. Thus, perivascular delivery of bFGF to the arterial wall was deemed more efficient than an IV injection.

The publication "Basic Fibroblast Growth Factor Improves Myocardial Function in Chronically Ischemic Porcine Hearts," by Harada K. et al., J. Clin. Invest 94; 94:623-630, Aug. 1994 discloses a study investigating the angiogenic effects of bFGF released from a heparin-alginate polymer which allows reliable and sustained delivery with first order kinetics over 4-6 weeks. The model was a porcine model of myocardial ischemia utilizing an ameroid constrictor to occlude the proximal LCX. At the same time as the placement of the ameroid, 4-5 calcium alginate capsules encapsulating heparin-seprose beads containing bFGF (1 ug per bead) were placed around the proximal LCX and proximal LAD.

The publication "Experimental Use of a Modified Fibrin Glue to Induce Site-directed Angiogenesis from the Aorta to the Heart," by Fasol R. et al., J Thorac Cardiovasc Surg 1994;108:1432-9 discloses a study of modified fibrin glue containing a-endothelial cell growth factor implanted in the heart between the aorta and myocardium in a rat model by means of a syringe after the thoracic aorta and myocardium of left ventricle were surgically exposed. Nine weeks after the implant procedure, angiography and histology confirmed the presence of new blood vessels in the animals treated with the growth factor.

It is respectfully submitted that none of the prior art now of record in this application discloses or suggests the subject matter as claimed in the subject application.

Respectfully submitted,

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COHEN & POKOTILOW, LTD.

November 5, 1999

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CERTIFICATE OF MAILING

I hereby certify that the foregoing INFORMATION DISCLOSURE STATEMENT, PTO FORM 1449 and a copy of each of the documents cited re Application Serial No. 09/369,107 are being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this 5th day of November, 1999.

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Barry A. Stein